

following regulations which will govern the licensing of rural health clinics.

#### Title 48

### PUBLIC HEALTH—GENERAL

#### Part I. General Administration

#### Subpart 3. Licensing and Certification

### Chapter 75. Licensing of Rural Health Clinics

#### Subchapter A. General Provisions

#### §7501. Definitions and Acronyms

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

*CLIA*—Clinical Laboratories Improvement Act—Requires a waiver or certificate to assure quality of laboratory testing.

*DHH*—Louisiana Department of Health and Hospitals  
*Division of Research and Development*—Office of Primary and Rural Health Care Unit in DHH.

*HCFA*—Health Care Financing Administration—federal regulatory agency for Medicaid, Medicare, and Child Health Insurance programs.

*HSS*—Health Standards Section in the Bureau of Health Services Financing of DHH.

*Midlevel Practitioner*—a certified nurse midwife, a certified nurse practitioner, or physician assistant.

*OMB*—Office of Management and Budget of the Executive Office of the President of the United States.

*OPH*—Office of Public Health in the Department of Health and Hospitals.

*OSFM*—Louisiana Office of State Fire Marshal.

*Primary Care*—services normally provided in a physician's office to diagnose, treat, or prevent illness or injury; and includes professional services provided by licensed professionals such as assessment, examination, approved laboratory services, and treatment services listed in §7519.

*Professional Services*—documented, face-to-face visit on the RHC premises for the purpose of providing professional level skilled services. Professional services include physical assessment, any of the waived clinical laboratory tests and treatment/education for the illness diagnosed when provided by a qualified professional as defined below.

*Qualified Professionals*—one of the following professionals qualified to provide services:

- Advanced Practice Registered Nurse*—APRN;
- Licensed Clinical Psychologist*—LP
- Licensed Physician's Assistant*—PA;
- Licensed Social Worker*—Board Certified Social Worker (BCSW);
- Physician*—Doctor of Medicine;

*Rural Area*—a non-metropolitan statistical area, as defined by the federal Office of Management and Budget and the Census Bureau/Population and Housing Unit Counts, which has a shortage of physicians and other health care providers as determined by the Department of Health and Hospitals.

*Rural Health Clinic (RHC)*—an outpatient primary care clinic seeking or possessing certification by the Health Care Financing Administration (HCFA) as a rural health clinic, which provides diagnosis and treatment to the public by a qualified mid-level practitioner and a licensed physician.

*Standards of Practice*—standards developed and issued by Louisiana professional practices boards that govern health care and allied health professions. Duties and delegation of duties by licensed/certified personnel shall be performed within the bounds of ethical and legal standards of practice. All patient care services must be provided in accordance with the orders of licensed and certified practitioners. Standards of practice pertinent to rural health clinic practice are listed in §7523 of this document.

*Waiver or Variance*—written permission granted by the HSS or DHH Secretary or his designee to a facility to operate out of compliance with a specific portion of the standards when it is determined that the health and safety of the patients will not be jeopardized.

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#### §7503. Licensing

##### A. General Provisions. Rural Health Clinics shall:

- operate in accordance with rules, regulations and standards contained in this document;
- meet and maintain compliance with all current HCFA conditions of participation and DHH Minimum Licensing Standards;
- maintain a sufficient number of qualified professional personnel to provide services appropriate to level of care and the number of patients served; and
- maintain at least \$500,000 of general liability insurance and \$500,000 of professional liability insurance and provide to DHH proof of insurance upon request.

##### B. Initial Licensing

###### 1. Policies

- All applications shall be original documents submitted to HSS in accordance with current procedures.
- Incomplete applications will be closed and discarded 90 days from date of original submission of data. An application is not considered pending until the day a complete application has been received and approved.
- Any misrepresentation or falsification of documentation will nullify the application and automatically restrict the applicant from participation in any programs licensed by HSS for at least one year.
- Fees or payments for charges submitted to HSS shall be in the form of a company check, certified check or money order made payable to DHH and are non-refundable and non-transferable.

###### 2. Procedures

- Obtain a packet from HSS (packet is informational and current for approximately 90 days from date of purchase).
- Complete an application form. Submit an original and one copy.
- Submit the appropriate licensing fee.
- Submit the following documentation:
  - all documentation pertinent to the proposed location from the Division of Research and Development, Office of Primary and Rural Health Care Unit and dated within 30 days prior to application;
  - written approval of site/building plans by DHH planning review section;

iii. required jurisdictional approvals—local, state, and federal such as zoning, Fire Marshal, and sanitation;

iv. letter of intent which shall include:

(a). proposed operational hours;

(b). proposed target population including clinic location, service area, and pertinent demographics;

(c). copy of site plan and sketch of the floor plan of the building;

(d). proposed date to begin operation;

(e). services to be provided;

(f). relationships and/or agreements with other entities (hospitals, emergency transportation, etc.);

(g). other licenses, contracts with state, such as Community Care, Kid Med, managed care, etc.;

v. appropriate CLIA approval prior to any initial survey.

3. Survey. Prior to issuing an initial license, DHH/HSS will make a comprehensive on-site assessment to determine the capability of the facility to provide primary care services. A facility shall be operational prior to survey and must have seen at least five patients at the time of survey.

#### C. Types of License

1. Full, Unrestricted. This license type indicates that the facility is in full compliance with licensing standards, and is valid for one year unless revoked, suspended, or denied. The license is non-transferable.

2. Provisional. This license type is issued for a specific length of time in order to designate that the facility is not in full compliance with licensing standards. A provisional license may be issued for the following reasons:

a. any repeat violation;

b. serious violation during any survey or on-site visit;

c. isolated incidence of non-compliance that has the potential for serious harm if not corrected immediately; or

d. determination that the facility has potential for serious violation or potential harm due to personnel turnovers, ownership changes, management changes, etc.

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HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1846 (October 1999).

#### §7505. Denial, Revocation, or Non-Renewal of License

A. In accordance with Subsection C. Adverse Actions, DHH reserves the right to suspend, deny (initial or renewal) or revoke any license at the discretion of the Secretary or his designee. Facilities, facility owners and staff shall be reported to the proper authorities such as state Licensing boards or state or federal enforcement agencies, when there is suspicion of illegal or unethical behavior.

B. Any involuntary termination, failure to renew, or voluntary termination of the facility's license to avoid pending adverse action will automatically prevent the facility and the facility owners, professional staff, administrative staff, family members and others as appropriate from applying for an RHC license, or from owning or working with a rural health clinic, for at least one year. Persons who own at least five percent or more of the facility are considered owners.

C. Adverse Actions. A license or renewal may be revoked, suspended, or denied for any of the following reasons:

1. cruelty or indifference to the welfare of the patients;

2. misappropriation or conversion of the property of the patients;

3. violation of any provision of this section or of the minimum standards, rules, and regulations or orders of the agency promulgated hereunder, including but not limited to, the following:

a. failure to employ and utilize a sufficient number of appropriately qualified professionals;

b. repeated failure to maintain adherence to any standard;

c. serious violation of RHC standards or current professional standards of practice by licensed/certified personnel;

d. failure to timely submit a corrective action plan for identified violations;

e. reasonable cause to suspect that patient health/safety is jeopardized;

f. reliable evidence that facility has:

i. falsified information on legal documents;

ii. failed to provide optimum therapy in accordance with current standards of practice;

iii. bribed, solicited or harassed any person to use the services of any particular facility; and

iv. failed to assure that only qualified professionals provided care and services;

g. failure to submit required fees in a timely manner;

h. failure to cooperate with survey/investigation by DHH/authorized agencies;

4. any owner of five percent or more of the agency and any administrative officer convicted of a felony or pleads *nolo contendere* to a felony charge. If the applicant is an agency, the head of that agency must be free of such conviction. If a subordinate employee is convicted of a felony, the matter must be handled administratively to the satisfaction of DHH/HSS;

5. documented information of past or present conduct or practices of facility which are detrimental to the welfare of the patients.

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HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1847 (October 1999).

#### §7507. Changes/Reporting

A. Data Submission. Information requests will be sent to the clinic by various offices of DHH or its contractors. All requests must be answered promptly and must be current at time of renewal or license will not be issued.

1. Each facility shall notify DHH/HSS if facility contracts to provide services under another program such as Community Care, Kid Med, managed care, etc.

2. Failure to return requested information shall result in adverse action including, but not limited to, sanctions, and/or revocation of license.

B. Notifications. The rural health clinic must notify HSS at least fifteen days prior to any operational changes. A license is non-transferable; therefore, invalid for any other

location or owner except as originally issued. Any break in the operation of the facility will invalidate the license.

1. Change of Ownership. The following information must be submitted:

- a. certified copy of bill of sale;
- b. application reflecting changes; and
- c. letter of intent, narrative explanation of changes.

2. Change of Address(Location). Submit the following information:

- a. same zip code:
  - i. letter for approval by DHH/HSS;
  - ii. Fire Marshal's approval;
  - iii. fee to re-issue license; and
  - iv. copy of current license;
- b. different zip code-site approval letter in addition to above requirements.

3. Change in Services. The following information must be submitted:

- a. letter to file listing current services; additional/deleted services;
- b. copy of license;
- c. professional and management staffing changes; and

d. use of contract mid-level practitioner instead of the employee for any period of time greater than 30 days or more than twice during the calendar year.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1847 (October 1999).

#### **§7509. Annual Licensing Renewal**

A. DHH Responsibilities. It is the responsibility of the Department of Health and Hospitals (DHH) to:

1. send a letter of notification of license renewal to the facility approximately forty-five (45) days prior to expiration of license;

2. survey annually to assure facility provides quality care, and adheres to licensing requirements;

3. assure that all legal requirements are met (e.g. cost reports, fire marshal reports, etc.); and

4. make a determination and take appropriate action regarding licensing.

B. RHC Responsibilities. It is the responsibility of the Rural Health Clinic to:

1. notify DHH if the renewal letter is not received in a timely manner;

2. complete the application and obtain and submit other required data; and

3. submit the appropriate fee for license.

C. Survey. DHH shall make an annual on-site survey. If DHH does not make an on-site survey prior to renewal of the license, then the facility shall be issued an extension of a valid license.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1848 (October 1999).

#### **§7511. Notice and Appeal Procedures**

A. Notification. DHH will give 30 days notice prior to revocation, suspension or denial. However, DHH will not give notice of denial of renewal, suspension, or revocation if

DHH determines that the health, safety and welfare of the patients is in jeopardy.

B. Appeal Requests. Facilities may appeal denial of initial or renewal license, revocation, or suspension. Appeals resulting from adverse action are suspense unless DHH determines that the patient's health/safety is in jeopardy. However, when the patient's health and safety is in jeopardy, appeal rights may be exercised only after the facility is closed.

1. Informal Dispute Resolution. Request must be submitted in writing to DHH-HSS within 10 (ten) days of receipt of the notice of adverse action.

2. Administrative Appeal. Request must be submitted in writing to DHH—Office of the Secretary within 30 (thirty) days of receipt of the notice of adverse action. Requests for informal disputes resolution does not affect the time frame for requesting an administrative appeal.

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HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1848 (October 1999).

#### **§7513. Complaint Procedures**

A. All complaints and appeals from complaints will be investigated by the HSS in accordance with Louisiana R.S. 40:2009.13 et. seq.

B. Deficiencies or violations noted during complaint investigations may result in adverse actions, sanctions, terminations, and/or require immediate or routine corrective action as determined by DHH.

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HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1848 (October 1999).

#### **§7515. Voluntary Cessation of Business**

A. Cessation of Business. If at any time the facility ceases to operate (regardless of length of time), the license shall be deemed invalid and shall be returned to DHH/HSS within five working days.

1. The agency owner is responsible for notifying DHH of the location of all records required to be maintained by the facility.

2. If the facility fails to surrender its license, the facility and its owners and administrative officers may be prohibited from operating for at least one year as a rural health clinic.

B. Expiration of License. Up to 30 days after the expiration date, failure to renew a license shall result in late fees. Thirty-one days or more after the expiration date, the facility shall be required to pay any fines or fees before applying for an initial license. Renewals will not be processed if received more than 31 days after the renewal date; the facility will be required to apply as an initial licensee.

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HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1848 (October 1999).

#### **§7517. Personnel Qualifications/Responsibilities**

A. Responsibility. The administration is responsible for assuring that:

1. all staff members are aware of their job responsibilities and are capable of performing assigned tasks;

2. a facility's staffing is adequate to produce the desired treatment outcomes and must reflect the volume of the patients, patient acuity, and number of services provided;

3. a facility develop and utilize a specific process to determine appropriate staffing levels.

B. Qualification. All personnel shall be licensed in accordance with their respective professions and be either board certified or board eligible as required by their respective certifying organizations. In addition, a facility shall be responsible for verifying and monitoring that professional certified personnel maintain continuous license/certification.

1. Physician Services. The physician shall provide on-site supervision of the mid-level practitioner(s) as required by the payment source and professional boards or at least every other week. All rural health clinic records and care provided by a mid-level practitioner(s) shall be assessed by a physician on a periodic basis or as the situation dictates to assure proper treatment and progress toward positive patient outcomes.

a. Medical Director. The medical director shall be credentialed to provide primary care. He/she is responsible for providing the medical direction for the clinic's activities, consultation for and supervision of the mid-level practitioner. The Medical Director, in conjunction with the mid-level practitioner, participates in the development and periodic review of the clinic's policies and services. He/She periodically reviews the patient records, issues medical orders and provides medical care services to the rural health clinic patients.

b. Other. Licensed physician credentialed to provide services provided as part of the rural health clinic services.

2. Mid-level Practitioner. The Mid-level Practitioner shall be appropriately licensed and credentialed as either an Advanced Practice Registered Nurse (Family Nurse Practitioner) or Physician's Assistant. The mid-level practitioner(s) shall be required to maintain ALS (ACLS and ATLS) certification to assure his/her proficiency in accepted standards of emergency care. If a facility has a written, current agreement with an advanced life support provider, who can provide care within ten minutes, then the mid-level practitioner and/or physician are exempt from this required certification.

a. Waivers will not be accepted for a mid-level practitioner.

b. Mid-level practitioners may be contracted to fulfill staffing requirements for 120 days each calendar year (January 1—December 31) with no accrual of days from year to year.

3. Support Staff. The facility should be adequately staffed to provide necessary support to the professionals. Additional staff may include pharmacists, administrators, managers, and clerical and medical records personnel.

C. Governing Body. All owners of a Rural Health Clinic shall be disclosed. Ownership of five percent or more constitutes ownership. In the case of a corporation, members of the board of directors must be identified and minutes of the board meetings shall be made available to DHH/HSS. The board shall meet at least once a year.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1848 (October 1999).

#### **§7519. Services**

##### **A. Preventive Services**

1. Health. Community-wide immunization efforts; wellness/fitness programs; educational programs; and health screening shall be provided.

2. Dental. Educational information and a current list of local dental providers shall be available.

B. Diagnostic Services. The clinic must have the capacity to evaluate and make initial diagnoses on-site in order to refer to the patient to the appropriate facility for treatment and/or more definitive diagnoses. RHCS shall meet the CLIA requirements for all laboratory tests. The clinic shall provide as part of professional services, any laboratory test that is essential to immediate diagnosis and treatment of illness and/or which can be performed by a method/procedure listed on the current list of waived tests by the CLIA requirements.

##### **C. Treatment Services**

1. Primary Care. The clinic shall provide primary care services, as defined in §7501 to all citizens of the community. Required primary care components include:

a. prevention of illness, education in wellness and preventive measures;

b. assessment and physical examination; and

c. diagnosis and treatment.

2. Emergency Care. The clinic shall maintain emergency equipment, medications and personnel to provide pre-hospital advanced cardiac life support and advanced trauma life support until emergency transportation can arrive and assume care of those in need of services.

a. Facilities within 10 (ten) minutes of Advanced Life Support (ALS) services may opt to have written agreement with a provider to provide services in lieu of certain equipment such as defibrillators and monitors, but must have equipment required for Basic Life Support.

b. All facilities shall have written agreement with emergency transportation provider to transport to the nearest hospital.

3. Contracted Treatment Services. Written agreements with full-service hospitals and credentialed practitioner(s) for specialty care must be current, clearly written, and reviewed annually. The facility retains responsibility for all medical care provided until the patient is referred to or admitted into another facility. Agreements must be signed and dated by all parties.

##### **D. Miscellaneous Services**

1. Family Services. The Rural Health Clinic shall maintain a current list of local/nearest support organizations and assist (whenever necessary) with accessing those entities. Examples of services that may be listed by the clinic shall include such organizations as the Public Health Unit, Office of Family Support, school clinics, hospices agencies, home health agencies, American Cancer Society, and services for substance abuse and mental illness.

2. Coordination of services for complex cases is the responsibility of the RHC professional staff.

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#### **§7521. Agency Operations**

A. Municipals. A facility shall function as a community resource for all citizens of the service area and shall promote improvement of the health of the entire community by providing educational opportunities where feasible, resource lists for referrals, assistance with accessing other resources, wellness programs, and participation in community efforts to promote health and safety. A facility shall demonstrate the following.

1. Telemedicine Capacity/Resource. Computer access is recommended.

2. Emergency Preparedness. A facility shall:

a. maintain a disaster plan appropriate to region and community;

b. have facility protocols for medical and non-medical emergencies;

c. maintain emergency supplies to provide basic emergency care in the case of a disaster in the community; and

d. participate in the development of local community disaster plan.

B. Agreements. Written agreements shall be clearly worded, dated, reviewed and signed by all parties at least annually. All agreements shall be updated as needed to reflect any changes in relationships, provision of services, or other pertinent information.

C. Operation Hours. A facility shall provide:

1. primary care services at least 36 hours per week; three (3) hours a week must be outside of the hours of 8:00 a.m. to 5:00 p.m. Monday through Friday. Priority access and mobile units may be exempt from this requirement if a written variance is approved by DHH-HSS;

2. on-call qualified professional assistance for 24 hours per day, seven days per week;

3. appropriately qualified professional staff on duty during all hours of operation. Failure to do so will result in immediate adverse action.

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HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1850 (October 1999).

#### **§7523. Procedural Standards**

A. The following processes are required for rural health clinics in Louisiana.

1. Access to Care. Rural Health Clinics shall:

a. not be located within facilities also housing other health care providers in accordance with Louisiana R.S. 40:2007;

b. be located away from metropolitan areas;

c. provide services to all citizens of the community across all life cycles;

d. provide service delivery to accommodate the majority of residents of the community; and

e. provide professional coverage as required by §7517 and §7519.C.

2. Patient Assessment. Documentation of an assessment shall include:

a. comprehensive scope of information with updates as indicated by changes in the patient's status;

b. physical examination and medical history, that identifies the patient's condition and care needs, and an estimate of his/her continuing care needs;

c. indicators that identify the need for further assessment/treatment such as the signs/symptoms of substance abuse, which requires a substance abuse assessment be included as part of the mental status evaluation; and

d. pertinent and comprehensive information relative to the reason for the encounter.

3. Care Planning. The plan of care shall be based upon the needs documented in the assessment and may be generic if original assessment and physical examination indicates the patient is generally healthy. The plan of care shall be modified to reflect any changes in the patient's condition.

4. Continuity of Care. The clinic staff shall:

a. provide orderly and efficient transition between levels of care without duplication or disruption of services;

b. provide post-hospitalization care based on the hospital's discharge assessment, possibly a Uniform Needs Assessment Instrument (UNAI), but includes at least a description of the patient's functional status, nursing and/or other care requirements, and the availability of family/care givers;

c. update comprehensive care plan as indicated and provide clinic services as indicated in the plan of care;

d. coordinate care and treatment interventions by all relevant disciplines;

e. evaluate progress and adjust actual care as needed to achieve progress.

5. Infection Control. A facility shall maintain a written and dated effective infection control program that protects the patients and staff from infections and communicable diseases.

6. Information Management. A facility shall maintain a record keeping system to communicate and measure clinic performance to assure that patient needs are documented and met. This system shall include accurate documentation of a patient visit for quality assessment and performance improvement purposes. The facility shall ensure the integrity, effectiveness, confidentiality, and security of the facility's data system.

7. Clinical Protocols. Written clinical protocols shall be established between mid-level practitioner(s) and the physician and the treatment(s) of choice shall be easy to identify.

8. The facility must have a grievance process and must indicate who the patient can contact to express a grievance. Records of all grievances, steps taken to investigate, and results of interventions must be available to surveyors upon request.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1850 (October 1999).

#### **§7525. Record Keeping**

A. Medical Records

1. Identifying Information. The patient identification information such as name or ID number must appear on each page.

2. Entry Identification. Entries must be dated, signed, and credentials identified (MD, RN, etc.).

3. Contents. Each patient record must contain the following:

- a. personal/biographical data including full name, age, sex, address, employer, home and work telephone numbers, and marital status;
- b. next of kin or contact person;
- c. pertinent medical history/information.

4. Storage. All medical records shall be protected from theft, fire, and unauthorized use. Open shelving may be utilized only when the patients/visitors do not have access to the storage area. Closed records must be maintained by the facility or its designee in accordance with the following:

- a. a minimum of seven years from the date of last entry. After two years, records may be maintained electronically;
- b. until the age of majority, plus seven years in the case of children or adolescents.

B. Facility Records. A facility must maintain records of credentials and other evidence that facility is in compliance with current standards of practice and licensing standards as listed below:

1. personnel records;
2. advisory board meeting minutes;
3. policies/procedures with annual approvals;
4. governing board meeting minutes; and
5. proof of hours worked for professional employees.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1850 (October 1999).

## **§7529. Quality Assurance**

### **A. Definitions**

*Scope of Care/Services*—a facility shall delineate their scope of practice to include:

- a. the range of services provided, including conditions prevented, managed, or treated;
- b. treatments and/or procedures provided;
- c. patient populations served;
- d. hours when care or services are provided; and,
- e. types of professional disciplines and/or specialists providing services.

*Evaluation*—the review and assessment of the quality and appropriateness is an important aspect of care. The review and assessment is designed to identify problems and develop procedures to prevent and resolve the problems.

*Important Aspects of Care*—clinical activities that involve a high volume of patients, that entail a high degree of risk for patients, or that tend to produce problems for staff or the patients are deemed most important for purposes of monitoring and evaluation.

*Monitoring*—a process of surveillance, and/or auditing to identify systemic or localized problem area(s) where improvement may be indicated.

*Performance Indicators*—the measurement tool used to monitor and evaluate the facility's quality of management, clinical services, and support functions.

*Pursuit of Opportunity to Further Improve Care*—applies pro-active efforts to identify and implement improvements.

*Quality Improvement*—a management led and patient focused systematic method of improving systems and processes. Its basis is a statistical process control.

*Quality of Patient Care*—the degree to which patient care services increase the probability of desired patient outcomes and reduce the probability of undesired outcomes.

### **B. Process**

1. Utilization Review. At least 10 percent of all encounters shall be reviewed quarterly by the medical director and/or physician member of the advisory board.

2. Internal Evaluation. Facility shall develop and conduct an annual internal evaluation process to provide necessary data to formulate a plan for continuous quality improvement/quality assurance.

3. Quality Assurance/Continuous Quality Improvement. The facility shall have ongoing programs to assure that the overall function of the clinic is in compliance with federal, state, and local laws, and is meeting the needs of the citizens of the area, as well as attaining the goals and objectives developed from the mission statement established by the facility.

4. Quality Improvement Program. The facility shall have a written quality improvement program that addresses at least the following elements:

- a. facility philosophy/mission/goals/objectives/scope of care/services;
- b. personnel roles/responsibilities/physician supervision/nurse practitioner, credentialing/re-credentialing policy/procedures/annual review/evaluation and drug policy and procedures;
- c. important aspects of care/quality of care studies;
- d. performance indicators relative to, but not limited to, identified problem areas of the clinic or healthy outcomes;
- e. monitoring and evaluation procedures/documentation of findings;
- f. patients' rights, responsibilities, grievance and appeal policies/procedures;
- g. utilization review/medical records audit; and
- h. patient satisfaction surveys.

5. Systemic Quality Improvements. A facility shall:

- a. participate in a continuous effort to improve its performance;
- b. focus on improving patient outcomes and patient satisfaction;
- c. have objective measures to allow tracking of performance over time to ensure that improvements are sustained;
- d. develop/adopt quality indicators that are predictive of desired outcomes or are outcomes that can be measured, analyzed and tracked;
- e. identify its own measure of performance for the activities it identifies as priorities in quality assessment and performance improvement strategy;
- f. conduct distinct successful improvement activities proportionately to the scope and complexity of the clinic operations;
- g. immediately correct problems that are identified through its quality assessment and improvement program that actually or potentially affect the health and safety of the patients;
- h. make an aggressive and continuous effort to improve overall performance of clinic and personnel; and
- i. use the process of improvement (identification of patient care and service components; application of

performance measures; and continuous use of a method of data collection and evaluation) to identify or trigger further opportunities for improvement.

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HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1851 (October 1999).

### **§7531. Patient's Rights and Responsibilities**

A. The facility shall provide education to personnel regarding patient rights during orientation at least annually, and post a copy of the patient's rights in a conspicuous place.

1. Patients of Rural Health Clinics shall have the right to:

- a. be treated equally and receive care without regard to age, sex, religion, race or creed;
- b. receive care that is not determined by patient's ability to pay for service;
- c. confidentiality of his/her clinical records;
- d. be informed of all costs and expected payment from other resources;
- e. be treated with respect for the individual patient's comfort, dignity and privacy;
- f. be informed of his/her rights in advance of care being provided;
- g. access information contained in his/her clinical records within a reasonable time frame;
- h. make decisions regarding his/her care;
- i. formulate advance directives and have staff/practitioners to comply with those directives;
- j. maintain personal privacy and receive care in a safe setting; and
- k. be free from verbal or physical abuse or harassment from staff.

2. Patients of Rural Health Clinics are responsible for:

- a. providing, to the extent possible, information needed by professional staff in caring for the patient;
- b. following instructions and guidelines given by those providing health care services.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1852 (October 1999).

### **§7533. Advisory Committee**

A. All members of the advisory committee shall be designated in writing and approved by the governing board. The advisory committee shall be composed of two medical professionals, and at least one consumer of services; none may be employed by the facility. However, facility staff should attend meetings.

1. Qualifications

a. Medical professionals may be any Louisiana licensed health care professional, including but not limited to, medical doctor, registered nurse, board certified social worker, pharmacist, or physical therapist.

b. Consumers must be members of the local community, over 21 years of age, and not affiliated by employment, family, finance or contract with the facility or its owners.

2. Responsibilities. The Advisory Committee shall:

- a. meet annually to review the facility's mission/philosophy, operations, finances, policies and

planned activities to assure that the facility is improving access and health care to the community; and

b. provide suggestions regarding facility changes based upon community needs, growth, and support.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1852 (October 1999).

### **§7535. Physical Environment**

A. Occupancy. The facility shall have written approval from the appropriate agency to verify compliance with Office of the State Fire Marshal.

B. Safety. The following are fundamental to the effective management of a facility:

1. preventing, reporting and correcting threatening situations, equipment failures, and actual incidents that involve injury or damage to property;
2. proper safety management;
3. emergency preparedness;
4. proper storage and disposal of trash and medical waste;
5. proper temperature control, light and ventilation;
6. proper storage of drugs and cleaning material; and
7. clean and free of hazards;

a. bathrooms shall be vented to outside and have adequate soap, hand towels and hot water to promote infection control;

b. general appearance of facility shall be neat and clean;

8. exits shall not be obstructed and facility shall have:

a. a minimum of two exits spaced as widely apart as possible;

b. exit doors that are at least 34 inches wide but less than 48 inches;

c. exit corridors that are at least 44 inches wide and do not pass through a storage room, mechanical room, or kitchen;

d. clearly marked exits and exit pathways with exit signs and arrows;

e. adequate light at all times. If the facility is occupied at night, all exit signs must be internally lighted and corridors must have emergency light units;

f. doors which can be opened from inside the room or area without a key or special knowledge; and

g. exit signs over each exit door and also at every corridor junction. At least one exit sign must be visible from any location in the building;

9. locks:

a. no door equipped with a self closure device (except entry/exit doors) may ever be blocked open;

b. every lock must be operable from inside the room or area;

10. miscellaneous:

a. the facility shall have one fire extinguisher (minimum size 2A) for each 1500 square feet. It must be inspected and tagged annually; and, the gauge must show in the white, green, or "overcharged" areas. It may be Type A or Type ABC;

b. Any storage room over 50 square feet must have an automatic door closure device. No flammable liquids (such as gasoline, diesel, etc.) may be stored inside the



facility. However, alcohol and cleaning supplies are allowed in reasonable quantities;

c. any compressed gas cylinder, regardless of type and/or amount of contents, must be on a rack or chained to avoid tipping;

d. at a minimum a fire wall rated for one hour must separate the facility from any other occupied area. Criteria for the wall include:

i. one layer of 5/8 inch fire code sheetrock or other limited or non-combustible material on each side;

ii. separation wall must extend completely to the roof deck with no unsealed penetrations or holes;

iii. one and 3/4 inch doors (if doors are present) must be solid core with automatic self-closure device.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2197.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 25:1852 (October 1999).

David W. Hood  
Secretary

9910#081

## RULE

### Department of Insurance Office of the Commissioner

#### Regulation 62—Managed Care Contracting Requirements (LAC 37:XIII.Chapter 53)

In accordance with the provisions of LA R.S. 49:950 of the Administrative Procedure Act, the Department of Insurance hereby adopts Regulation 62. The purpose of this regulation is to implement the standards of and assure compliance with Acts 897 and 1495 of the 1997 Regular Session of the Louisiana Legislature which provide for the required participation of qualified rural hospitals and their practicing physicians, through the establishment of reasonable contracting requirements for medical services, that do not jeopardize the health of enrollees or plan members. This regulation took effect on March 20, 1999.

#### Title 37

#### INSURANCE

#### Part XIII. Regulations

#### Chapter 53. Regulation 62—Managed Care Contracting Requirements

##### §5301. Purpose

A. The purpose of this regulation is to establish the reasonable authority and obligation of managed care organizations related to provider contracts under Acts 1485 and 897 of the 1997 Regular Session of the Louisiana Legislature. The provisions of LA R.S. 40:1300.125 and LA R.S. 40:1300.145 establish the legislative intent for qualifying rural hospitals, and their practicing physicians, to be allowed to participate in the health care delivery systems of managed care organizations. These statutes also establish the intent of the legislature that managed care organizations provide reasonable reimbursement for the services provided by qualifying rural hospitals and the physicians who practice at these hospitals.

B. Act 897 of the 1997 Regular Session of the Louisiana Legislature amends Titles 40 and 22 of the Louisiana Revised Statutes to prohibit managed care organizations from using incentive arrangements that impede, impair, or otherwise diminish the ability of a plan member or enrollee to receive appropriate and necessary medical care and treatment. These statutes also establish the legislative intent that any prohibitions on the authority of an insurer to contract for delivery of health benefits through capitation or shared risk arrangements be limited to non-compliant incentive arrangements. To carry out the intent of the legislation and assure full compliance with the provisions of these Acts, this regulation establishes reasonable contracting requirements that are applicable to managed care organizations and assures uniformity in application of terms and conditions for participation.

AUTHORITY NOTE: Adopted in accordance with R.S. 22, R.S. 22:3, R.S. 22:215.18, 2:2006, 22:2014, 22:2018, 22:2019, 22:2021 and 22:2022.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 25:1853 (October 1999).

##### §5303. Definitions

*Accreditation/Certification*—a hospital that is accredited by the Joint Commission on Accreditation of Health Care Organizations (JCAHO) or Medicare certified for provision of acute care hospital services.

*Community*—the parish in which a qualifying rural hospital is located.

*Discriminate*—to apply a payment methodology that relies upon terms and conditions that are more restrictive than those terms and conditions applicable to non-rural hospitals or their practicing physicians in a region which result unreasonable payment to a qualifying rural hospital or physician practicing in such hospitals. A payment methodology that results in reimbursement to a qualifying rural hospital or practicing physician that is equal to or greater than the reimbursement to non-rural participating hospitals or physicians in the region, shall be considered non-discriminating.

*Employee*—a person employed directly by a managed care organization and does not include any contract, temporary, or other type of employment arrangement.

*Geographic Area*—a Parish.

*Health Benefit Plan*—any health insurance policy, plan, or health maintenance organization subscriber agreement, issued for delivery in this state under a valid certificate of authority by an entity authorized by law to bear risk for the payment of health care services.

*Health Care Provider*—a physician duly licensed to practice medicine by the Louisiana State Board of Medical Examiners, or other health care professional duly licensed in Louisiana, or an acute care hospital licensed to provide medical care in this state. The term shall also mean any legal entity or organization formed for the primary purpose of providing medical or health care services and provides such services directly or through its participants.

*Incentive Arrangement*—any payment or contractual obligation included in a general payment plan, capitation contract, shared risk arrangement, or other agreement